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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ADAMS, AMANDA S	
ART UNIT	**PAPER NUMBER**
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,498	GOLESWORTHY ET AL.	
	Examiner	Art Unit	
	Amanda Adams	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32, 33, and 35* is/are allowed.

6)☒ Claim(s) *1-31,34 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 2, 4-10, 15, 16, 18-22, and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al (US 6,648,911).

3. Sirhan et al disclose the invention substantially as claimed including a stent for locations exteriorly of a blood vessel, that can be formed in morphological relationship with a blood vessel, and means for maintaining the stent in relationship with the vessel (col. 9, lines 35-40), forming the stent from a sleeve of at least two parts, the sleeve being generally of cylindrical form (col. 8, lines 54-65), the sleeve provided with appropriately located recesses or apertures for accommodating other interconnecting

arteries (col. 11, lines 50-62), the interconnection of the parts of the sleeve effected by a hinge mechanism with releasable latches provided at the mating edges of the parts (col. 9, lines 35-42), wherein at least one spiral part is adapted in use to locate over and coil around the blood vessel to provide in position the morphological relationship with the blood vessel (col. 6, lines 2-4), and wherein each spiral part is provided with inter-engaging means for connection to an adjacent part (col. 7, lines 16-20) and the spiral forming an open coil or a closed coil around the blood vessel (col. 9, lines 1-12). Sirhan et al also disclose the inner surface of the stent to be of a smoothness to ensure that no fretting or abrasion occurs and the external surface of the stent is tolerant of other adjacent body parts (figs. 14-16, the inside surface is shown to be smooth). Sirhan et al further disclose that the material from which the stent is produced is resistant to the effects of electromagnetic fields (col. 6, lines 20-28; plastics are not electromagnetically sensitive), that the stent can be produced from a material that is thermally stable and biocompatible (col. 6, lines 20-28), and that the stent can be produced from any material that is composed of or a mixture of polymeric, metallic, or ceramic (col. 6, lines 20-28). Sirhan et al also disclose that the stent is adjustable in situ (col. 12, lines 4-10).

4. Regarding claim 5, Sirhan et al further disclose that there is a base or flange portion adapted for attachment to a main heart structure such that a securement or anchor point is established for the stent, the base or flange portion being adapted for appropriate attachment to the said structure (col. 2, lines 50-56).

5. Regarding claims 7-10, Sirhan et al further disclose that the sleeve of the stent is slit longitudinally to allow it to be expanded over the wall of the artery and then to

recover its original condition, the sleeve being suitably clampable in position embracing the artery in a morphological relationship (figs. 15A and 15B, notice how the sleeve edges overlap; the edges are created by a longitudinal slit), the clamping is achieved by the application of suitable ties and there are one or more grooves with the sleeve for receiving and locating the ties (col. 8, lines 25-30), and the clamping can be effected by the insertion of a locking pin extendable through hinge elements provided at the mating edges of the slit in the sleeve (col. 9, lines 35-42).

6. Regarding claims 20 and 25, Sirhan et al disclose that the material from which the stent is made from can be a heat shrinks plastic (col. 6, lines 20-25) or a translucent material (col. 6, line 66 – col. 7, line 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911).

9. Due to lack of criticality in the specification, the inter-engaging screw connection was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to any other means of inter-engaging. Therefore, it would have been obvious to make the means of interengaging between the spiral stent

components be a screw connection because it is capable of working equally as well as a locking pin and hinge elements.

10. Claims 3, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of Shifrin et al (US 5,476,471).

11. Sirhan et al disclose the invention substantially as claimed above except for failing to disclose the following which is taught by Shifrin et al. Shifrin et al teach a stent sleeve that includes one or more sections of varying form in order to conform to the morphological requirements in any particular case, that the sleeve can have varying thickness with the greatest thickness being provided in the base or flange region, such that the reduction of thickness moving away from the base region allows the degree of flexibility needed to accommodate the pulsing of blood through the artery. (col. 4, lines 44-45). Varying the thickness and flexibility of the stent in this manner allows it to have a better conforming capability to achieve a better morphological fit between the implant and vessel. It is also old and well-known in the art to have a stent graft be capable of both flexing and providing structural support. Therefore it would have been obvious to vary the thickness of the stent with the thicker end being near the base or flange region.

12. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of Doorly et al (US 6,554,856).

13. Sirhan et al disclose the invention substantially as claimed above but fails to disclose the following, which is taught by Doorly et al. Doorly et al teach an outer and inner casing wherein the outer casing is of more rigid construction that the inner casing and wherein the inner casing is of petal-like form (col. 3, lines 56-59; fig. 2, [2] are the

petal-like forms). Varying the flexibility of the stent in this manner allows it to have a better conforming capability to achieve a better morphological fit between the implant and vessel. It is also old and well-known in the art to have a stent graft be capable of both flexing and providing structural support. Therefore it would have been obvious to have the inner and outer casings of different rigidities and to have petal like forms to allow a better morphological fit between the stent and vessel.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of Kocur et al (US 2002/0103527).

15. Sirhan et al disclose the invention substantially as claimed above but fails to disclose the following, which is taught by Kocur et al. Kocur et al teach that it is old and well-known in the art for a stent to deliver therapeutic substances such as antibiotics that are gradually releasable over time. The device of Sirhan et al has already disclosed that it can be made of biodegradable materials that gradually biodegrade over time, and a well-known purpose of this is so that therapeutic substances can be released. Therefore it would have been obvious to have gradually released antibiotics incorporated into the stent.

16. Claims 27-31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of D'Urso (US 6,112,109).

17. Sirhan et al disclose the invention substantially as claimed above but fails to disclose the following method, which is taught by D'Urso.

18. Regarding claims 27-29, D'Urso teaches a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized

model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5, lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36).

19. Regarding claims 30 and 31, D'Urso additionally teaches that a stent can be generated in the form substantially in which it is to be deployed in a surgical procedure (col. 5, lines 64-65) or that a precursor to the stent could be taken instead, in which case a mold would be taken of the precursor and then the stent formed in that mold (col. 5, lines 66-67).

20. Regarding claim 36, D'Urso teaches that these method steps are applicable to all types of implants, and does specifically include vascular implants (col. 9, lines 54-60) and can be used to make a stent as disclosed by Sirhan et al.

21. These are all commonly known methods of producing an implant with as close of a morphological fit as possible, which helps prevent damage to the interior of the patient's body. Therefore it would have been obvious to employ these methods to create a stent with a morphological fit.

22. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (US 6,112,109) in view of Nakayama et al (US 2006/0036311).

23. D'Urso discloses the method substantially as claimed including a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of

producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5, lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36). D'Urso fails to disclose that the shell of the stent is machined to provide perforations. However, Nakayama teaches a method wherein the shell is mounted in a computer numerically controlled machine having multiple axes control and is machined to provide appropriate perforations to accommodate the subsidiary blood vessels (par. 93 and claim 22). Machining the perforations allows precise control in the manufacturing process so that the perforations in the stent align correctly with the subsidiary blood vessels, thus providing a morphologically correct fit. Therefore it would have been obvious to have the shell perforated in this manner.

Allowable Subject Matter

24. Claims 32, 33, and 35 are allowed. No combinations of the prior art disclose or fairly suggest all f the limitations of these claims, particularly the steps of embroidering the stents.

Response to Arguments

25. Applicant's arguments filed 4/2/2007 have been fully considered but they are not persuasive.

26. Regarding Sirhan as prior art for claims 1-26, Sirhan is still acceptable prior art because although the device is not disclosed to be used particularly with the ascending aorta, it is disclosed to be used for a variety of blood vessels, which means it is capable of being used to be placed externally of the ascending aorta. Further, whether or not the device of Sirhan is used to be placed around the existing blood vessel or to replace a blood vessel is also not relevant in a device claim, as it is capable of being placed around the vessel.

27. Regarding Shifrin as prior art, the rejections over Shifrin are still maintained for similar reasons; because the device is capable of the same functions as the applicants claims.

28. Regarding Doorly as prior art, the rejections are maintained because Doorly was found in the search results for search regarding the same art as the applicants instant application. Therefore one would look to the art of Doorly for obviousness.

29. Regarding D'Urso as prior art for the method claims, the limitations of claim 1 are no longer required, therefore the rejections are maintained.

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 6/12/07

GLENN K. DAWSON
PRIMARY EXAMINER